DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 29, 2014

Sorin Group Italia S.r.l
% Mr. Fabio De Pasquale
Acting Director, Regulatory Affairs
5005 North Fraser Way
Burnaby, V5J 5M1 CA

Re: K142221
Trade/Device Name: MEMO 3D ReChord Semirigid Annuloplasty Ring
Regulation Number: 21 CFR 870.3800
Regulation Name: Annuloplasty Ring
Regulatory Class: Class II
Product Code: KRH
Dated: August 6, 2014
Received: August 12, 2014

Dear Mr. De Pasquale,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142221

Device Name
MEMO 3D ReChord Semirigid Annuloplasty Ring

Indications for Use *(Describe)*
MEMO 3D ReChord device is intended for correction of mitral insufficiencies or steno-insufficiences.

The use of the MEMO 3D ReChord device is indicated for correction of congenital or acquired mitral insufficiencies with dilatation and deformation of the mitral annulus. Type I insufficiencies, with no manifest lesions in the subvalvular apparatus, can be treated with the implant of the annuloplasty ring on its own. For type II insufficiencies, characterised by valve prolapse sustained by elongation/ breakage of the chordae tendineae and papillary muscles, and type III insufficiencies, characterised by partially immobilised leaflets due to the fusion/hypertrophy of the chordae tendineae, the device implantation must be accompanied by corrective valvuloplasty.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

(in accordance with 21 CFR 807.92)

510(k) Number: **K**142221

I. Submitter Information

Submitter: **Sorin Group Italia S.r.l.**
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Date Prepared: August 6th, 2014

II. Device Name and Classification

Proprietary Name:	MEMO 3D ReChord Semirigid Annuloplasty Ring
Common/Usual Name:	Ring, Annuloplasty
Classification Name:	Annuloplasty Ring
Regulation Number:	21 CFR 870.3800
Product Code:	KRH
Classification:	Class II
Classification Panel:	Cardiovascular

III. Predicate Device

The MEMO 3D ReChord Semirigid Annuloplasty Ring is substantially equivalent to its cleared predicate device identified below. Both devices have the same fundamental scientific technology and intended use:

510(k) Number:	K071327
Proprietary Name:	MEMO 3D Semirigid Annuloplasty Ring
Common/Usual Name:	Ring, Annuloplasty
Classification Name:	Annuloplasty Ring
Regulation Number:	21 CFR 870.3800
Product Code:	KRH
Classification:	Class II
Classification Panel:	Cardiovascular

IV. Device Description

Like its predicate device (the MEMO 3D Semirigid Annuloplasty Ring, K071327), the MEMO 3D ReChord Semirigid Annuloplasty Ring is supplied as a sterile, non-pyrogenic ring pre-mounted on a disposable holder.

Both the predicate and subject device are manufactured by embedding a superelastic metallic alloy inner core with medical grade silicone.
The resulting silicone sheath around the inner core is then encased within a tubular knitted fabric coated with a thin layer of turbostratic carbon (Carbofilm™). The fabric is then sewn along its length with a Carbofilm™ coated polyester thread.

The MEMO 3D ReChord features a fully removable system (the ReChord System) in the posterior curve of the annuloplasty ring, composed by a series of loops made by a single piece of yellow surgical thread retained in place by a single piece of blue surgical thread.

The ReChord System is designed to provide a temporary reference element to facilitate the sizing of the artificial chord length at the annular plane level when performing the replacement of mitral chordae tendineae in concomitance with the implant of the annuloplasty ring.

Both ReChord System threads end with a knot protruding from the ring surface, which is pulled at the end of the implant procedure to remove the threads from the ring. The annuloplasty ring is attached to a disposable holder (i.e., the two-piece holder) composed of a polysulfone disk and a polyetherimide template.

The disk attaches to a handle accessory and allows device handling, whilst the template keeps the device sufficiently stiff during suturing.

The MEMO 3D ReChord Semirigid Annuloplasty Ring is available in sizes 24 mm through 38 mm, in 2 mm increments. The number of the ReChord System thread loops varies based on the size of the annuloplasty ring: six (6) loops for ring sizes 24-30, eight (8) loops for ring sizes 32-38.

A complete set of accessories instrumentation is available separately to properly size the annulus and implant the annuloplasty ring.

V. Indications for Use

MEMO 3D ReChord device is intended for correction of mitral insufficiencies or steno-insufficiences.

The use of the MEMO 3D ReChord device is indicated for correction of congenital or acquired mitral insufficiencies with dilatation and deformation of the mitral annulus. Type I insufficiencies, with no manifest lesions in the subvalvular apparatus, can be treated with the implant of the annuloplasty ring on its own. For type II insufficiencies, characterised by valve prolapse sustained by elongation/ breakage of the chordae tendineae and papillary muscles, and type III insufficiencies, characterised by partially immobilised leaflets due to the fusion/hypertrophy of the chordae tendineae, the device implantation must be accompanied by corrective valvuloplasty.

VI. Substantial Equivalence Discussion

Table 1 presented in the following page compares the characteristics and features of the MEMO 3D ReChord to its predicate device.

Table 1 – Comparison with the predicate device

MEMO 3D ReChord characteristic / feature	Predicate Device 510(k) #	Predicate Device Proprietary Name	Device Equivalence
– Intended Use / Indications for use – Anatomical site for implantation – Target population	K071327	MEMO 3D Semirigid Annuloplasty Ring	The intended use and indications for use reported in the device labeling are the same between the MEMO 3D ReChord and the predicate device. The anatomical site for implantation and surgical access of the MEMO 3D ReChord annuloplasty ring are the same with respect to the predicate device. The replacement of mitral chordae tendineae is a common procedure which is routinely performed in concomitance with annuloplasty ring implant. The addition of the ReChord System is only intended to provide a reference point to facilitate surgeons in performing a concomitant procedure which is already carried out when implanting the predicate device; therefore, the proposed changes do not affect the patient population.
– Physical characteristics – Device design and materials – Safety and performance			The MEMO 3D ReChord annuloplasty ring, in its final implant configuration, is identical to the predicate device; thus, the safety and performances of the implantable device are unaffected by the proposed changes. The additional components introduced on the ring (i.e. the ReChord System threads) are made of standard surgical sutures which are removed in the course of the implant procedure. The introduction of the disposable two-piece holder and handle accessory does not affect the device function (i.e. it only ensures correct ring position during storage / transport and allow device handling).
– Product packaging and sterilization			The MEMO 3D ReChord utilizes the same sterile barrier (double polysulfone container) currently qualified and in use for the predicate device. The MEMO 3D ReChord is steam-sterilized using the same process in the same facility with respect to the predicate device.

VII. Non-Clinical Performance Data

Sorin Group Italia S.r.l. has conducted verification and validation testing of the MEMO 3D ReChord based on the risk analysis for the device.

Non-clinical testing included:

- extraction tests for the ReChord System threads and disposable holder;
- biocompatibility testing for the ReChord System thread and disposable holder components;
- simulated distribution testing; and
- simulated use testing (wet lab on isolated porcine hearts).

Ultimate tensile strenght, suture pull-out, rigidity determination, computational stress analysis, fatigue and durability testing, corrosion resistance, biocompatibility on the implanted materials and shelf life testing were previously conducted on the predicate device MEMO 3D and, since the implanted annuloplasty rings are identical, were not repeated for the MEMO 3D ReChord.

VIII. Clinical Performance Data

No clinical testing was conducted in support of the MEMO 3D ReChord Semirigid Annuloplasty Ring, as the indications for use are equivalent to those of its predicate device MEMO 3D.
These types of devices have been on the market for many years with proven safety and efficacy of use. The non-clinical testing referred to in this submission supports the substantial equivalence of this device.

IX. Statement of Substantial Equivalence

The MEMO 3D ReChord Semirigid Annuloplasty Ring has been demonstrated as safe and effective for its intended use as the legally marketed predicate device.
With respect to intended use and technological characteristics, the MEMO 3D ReChord Semirigid Annuloplasty Ring is substantially equivalent to the legally marketed predicate device.